REMARKS

It is not believed that this response occasions any fee, but should there be any fee, please charge same to Deposit Account No. 10-9750/MCP0274/TT.

Claim 16 is amended to provide the term "a particle."

It is submitted that no new matter has been added by the above amendments.

Claims 1-20 are currently pending in the captioned application.

Indefiniteness Rejection

Claim 16 was rejected under 35 USC §112, second paragraph. (Part of Paper No./ Mail Date 05242005 at 2.) In making the rejection, the Examiner asserted that Claim 16 recites the limitation "the particle' in line 1 and that claim 1 does not recite particle size. Therefore, the Examiner concluded that there is insufficient antecedent basis for this limitation in the claim (*Id.*).

Claim 16 has been amended in view of the Examiner's position concerning the lack of the explicit word "particle" in claim 1. It is believed that this ground of rejection is now moot and should be withdrawn.

Anticipation Rejections

Claims 1, 3-6, 10, and 17-19 were rejected under 35 USC §102(b) as anticipated by Harbit, US Patent No. 3,108,046 ("Harbit"). (Part of Paper No./ Mail Date 05242005 at 3.)

For the reasons set forth below, the rejection, respectfully is traversed.

Harbit discloses

> This invention relates to the method of making a high dosage sustained release orally administrable tablet and to the product of this method. More particularly, this invention provides a versatile, simplified method of preparing sustained release tablets with a high degree of control of the rate of drug release.
>
> Prior to this invention various methods have been Col. 1
>
> with poorly water soluble, high dosage drugs, that permit-
> ting a higher dose of drug per tablet. Another advantage of this novel invention is that by spraying the wax on the granulation it is possible to utilize a positive, effective quantity of sustained release material thereby achieving the desired release rate with lesser quantities of wax, i.e., again making it possible to incorporate more drug in each tablet. In contrast to the approximately 30% minimum amount of sustained release material needed in the prior art sustained release tablets, the applicant can use a minimum amount of 2% and get ever release rates over a prolonged period of time. Col. 2

In accordance with this invention the time delay material is a lipid material which is solid at room temperature, but has a low melting point of from 40° C. to 150° C. preferably 60° C. to 110° C. and is also nontoxic and pharmaceutically acceptable.

The time delay material is a substantially water insoluble material resistant to disintegration in the gastrointestinal tract and providing for a gradual release of the medicament in said tract. The time delay material may be, for example, a wax, a fatty acid, alcohol or ester, alone, or an admixture thereof.

The wax may be paraffin wax; a petrolatum wax; a mineral wax such as ozokerite, ceresin, utah wax or montan wax; a vegetable wax such as, for example, carnauba wax, Japan wax, bayberry wax, flax wax; an animal wax such as, for example, spermaceti; or an insect wax such as beeswax, Chinese wax or shellac wax. Col. 3.

In making the rejection, the Examiner contended only that:

> Harbit discloses a high dose tablet comprising from about 75% to about 98% drug and wax, such as paraffin wax or shellac wax (column 3, lines 1-31). The tablet dosage further comprises lubricant (column 4, lines 9-19). The dosage form provides both immediate release and sustained release (column 4, lines 21-31).

Part of Paper No./ Mail Date 05242005 at 3.)

As is well settled, anticipation requires "identity of invention." Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim.

Furthermore, in a §102(b) rejection there must be no difference between what is claimed and what is disclosed in the applied reference. Moreover, it is incumbent upon the Examiner to ***identify wherein each and every facet*** of the claimed invention is disclosed in the applied reference." The Examiner is required to point to the disclosure in the reference "***by page and line***" upon which the claim allegedly reads.

The rejection fails to identify where in Harbit each and every element of the rejection claims is shown. For example, the rejection fails to state where the affirmatively required "powdered wax" is disclosed. That was the Examiner's burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

As to claim 5 the Examiner failed to state where the affirmatively required disclosure of a "tablet [that] is substantially free of water-soluble, non-saccharide polymeric binders" is to be found in Harbit. That was the Examiner's burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

As to claim 6 the Examiner failed to state where the affirmatively required disclosure of a "tablet [that] is substantially free of hydrated polymers" is to be found in Harbit. That was the Examiner's burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

As to claim 18, the Examiner failed to state where the affirmatively required disclosure of a "tablet [that] is substantially free of water-soluble, non-saccharide polymeric binders" is to be found in Harbit. That was the Examiner's burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

As to claim 19, the Examiner failed to state where the affirmatively required disclosure of a "tablet [that] is substantially free of hydrated polymers" is to be found in Harbit. That was the Examiner's burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

As to claim 20, the Examiner failed to state where the affirmatively required disclosure of an "active ingredient is in its native crystalline form" is to be found in Harbit. That was the Examiner's burden. Because the Examiner failed to satisfy that burden the rejection is improper should be withdrawn.

Even further, the rejection does not point out where there is a disclosure of the required powdered wax in a swallowable immediate release tablet and a swallowable immediate release tablet meeting the USP dissolution specifications for immediate release tablets containing said active ingredient. Nor is it believed that the Examiner could make such a showing because Harbit discloses using wax in a controlled release formulation, not in an immediate release formulation. For this additional reason, the rejection is improper and should be withdrawn.

Claims 1 and 4-10 were rejected under 35 USC §102(b) as anticipated by Cheng, US Patent No. 6,099,859 ("Cheng"). (Part of Paper No./ Mail Date 05242005 at 4.)

For the reasons set forth below, the rejection, respectfully is traversed.

Cheng discloses